

## **Summary of the Quality Systems Committee Meeting January 13, 1998**

The Quality Systems Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Tuesday, January 13, 1998, at 10:30 a.m. Eastern Standard Time (EST) as part of the Third NELAC Interim Meeting in Arlington, VA. The meeting was led by its chair, Ms. Silky Labie of the Florida Department of Environmental Protection. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to address changes to the wording in NELAC Chapter 5, briefly discuss the status of the Performance Based Measurement Systems section, and to address general comments from meeting participants.*

### **INTRODUCTION**

Ms. Labie identified the goals the Quality Systems Committee has had since the July conference. These were to: (1) clarify the standards, (2) refine the standards by removing redundancies, improving consistency in terminology, and address air measurement issues by establishing an air subcommittee, (3) ensure that the standards are auditable, and (4) ensure consistent application of the standards throughout states. A list of potential members for the Air Subcommittee has been developed .

Additional issues that the committee has addressed include: (1) meeting the different needs of EPA program areas (this work is ongoing, language should be incorporated into Chapter 5 by June), (2) addressing vague terminology such as “where applicable” and “where relevant” to make the language more specific and therefore more auditable, and (3) addressing Performance Based Measurement Systems (to be discussed at this meeting).

Proposed amendments to the text are: (1) clarify definitions in Appendix B, (2) make consistent use of terms, (3) remove redundant terms, and (4) clarify issues such as documenting employee proficiency and documentation requirements for standards and reagents.

New issues the committee considered were: (1) national security issues, (2) electronic records retrieval, (3) reporting results near the MDL, and (4) corrective actions for surrogates.

Future projects for the committee are: (1) addressing definitions and methods for determining MDLs, (2) revising the methods to determine appropriate calibration procedures, and (3) establishing a national set of data qualifiers.

Comments on Chapter 5 should be sent to Ms. Labie no later than Feb 15, 1998, to be considered for the next NELAC conference.

A general comment was made that Chapter 5 should address four main issues: (1) require that laboratories have functioning systems so that data is of known quality and it meets the needs of the client (2) focus on what a laboratory needs to accomplish rather than how to do it, (3) be flexible and encourage cost effective approaches, and (4) foster good science. The standards

should focus on the core requirements of a good quality system and additional requirements from the client are addressed as part of meeting the needs of the client.

The committee felt these issues and goals are in agreement with the focus of Chapter 5. The committee is trying to balance flexibility with the need to provide enough detail so that the standards can be consistently applied.

## **CHANGES TO APPENDIX B (DEFINITIONS FOR QUALITY SYSTEMS)**

The hierarchy for selecting definitions in this appendix was first from the ISO Guide 25 , next the ANSI/ASQC E4-1994 Standard, then the EPA Quality Assurance Division Glossary and finally other sources such as the dictionary and committee-defined terms. These documents are referenced in the NELAC Glossary.

For the purposes of this chapter, matrices are defined in Appendix B as eight matrix types.

In the definition of Laboratory Control Sample and Quality Control Sample, the term uncontaminated vs clean is unclear. This should more clearly indicate that the terms refer to being free of the analyte of interest.

The definition of a Laboratory Control Sample refers to a lab fortified blank or a blank spike that is a control for the entire measurement process and not specific to any matrix.

Terms that were deleted were generally redundant, merged with others, or terms that were not used in the body of Chapter 5.

## **WHERE RELEVANT AND WHERE APPLICABLE ETC.**

The majority of the changes to eliminate the vague terms such as “where relevant” and “where applicable” were done to improve the auditability of these standards.

The comment was made that in general, “where applicable” could be stated as applying unless a client determines it is not necessary.

In Section 5.9.2.b, “where applicable” may need be changed to “where available”. The committee will revisit this wording.

The requirements in Section 5.9.4.2.1.b are not intended to require the lab to recreate the manufacturers’ certification procedures but to meet the specifications established by the manufacturer for calibration. The comment was made that these requirements should be determined by the specific DQOs for a client.

A question was raised about the amount of detail in Section 5.13. The numbered elements in Section 5.13 were taken from the ISO Guide 25 and modified to make this section applicable to environmental measurements. This is consistent with the original desire to incorporate all of the ISO 25 Guide language into Chapter 5.

The comment was made that Section 5.13.a.15 should reference the CBI procedures outlined in the *Code of Federal Regulations*.

## **REWORDING CHANGES**

In Section 5.5.2, the assumption was made that a national security issue relating to environmental laboratories would be determined by the Department of Defense in their relationship with the laboratory.

The rewording of Section 5.6.2.c.3 was intended to provide additional means to demonstrate an analyst's performance. This section needs to be revised to clarify situations where different analysts perform different phases of an analysis. Each analyst is not required to demonstrate proficiency in the whole method, but only the portion for which they are responsible. The committee also needs to clarify what is meant by "significant change in personnel" and how this relates to demonstrating performance.

For Section 5.10.1.2, paragraph C was added for small laboratories so, where necessary, they may simply modify an existing procedure without rewriting the entire document. This also makes it easier for the auditor. Paragraph C will be moved under paragraph B to avoid confusion and the requirement for keeping changes to procedures in an appendix will be deleted.

Section 5.10.5 was changed to distinguish between types of records needed for calibration standards versus reagents used for the sample analysis. Section 5.10.5.a will be amended to allow for recertification of material after the expiration date. Recording the date of receipt was required instead of the date of opening the container to simplify record keeping.

Section 5.12.2 added language covering the ability to retrieve data even if the technology used to generate it changes. This section also requires a plan for recovering records in the event a lab closes.

Section D.1.1.b.3 added corrective action in case of poor surrogate recovery

In Section D.1.4.c the term practical quantitation limit is not used because too many definitions exist for this term. This section covers two different issues, defining the quantitation limit and how to handle results below this limit. This section will require additional consideration. A suggestion was made to review the MDL definition used by the Army Corps of Engineering

## **PERFORMANCE BASED MEASUREMENT SYSTEMS (PBMS)**

Ms. Labie wanted opinions on whether Appendix E covering PBMS is ready to be incorporated into the Chapter 5 standards. The consensus was that the PBMS Appendix is not ready for adoption because PBMS has not been implemented within EPA. The PBMS Appendix may apply to modifications to all test methods except those that are method-defined (such as BOD).

## **GENERAL COMMENTS**

The comment was made that the record keeping requirements for the disposal of hazardous samples are excessive. The QS standards should only require that a plan for disposal be in place but not specify this level of detail. However, these requirements may help the client for the purposes of tracking a potentially hazardous waste. Another useful piece of information to record is the date from which the sample is no longer considered a sample for reanalysis and becomes a waste.

Some permitted facilities have compliance limits at the MDL level. In these cases, detecting an analyte could indicate being out of compliance with a permit. The requirement for verifying the MDLs could then affect the associated permit especially if the laboratory MDL decreases.

In Section 5.13.b.2, reporting requirements should be determined by the needs of client. The level of detail specified is excessive. Reporting to satisfy a client's needs may be very limited (i.e., whether or not they are in compliance or not). The information in the standard should be maintained but not necessarily reported to the client. Another issue is what is considered to be a regulatory report for the purposes of this chapter. The committee will revisit this section.

In Section 5.5.4.d, the driving force for determining the essential QC measures should be the DQOs and the client's needs and not necessarily meeting Appendix D. The committee was attempting to define essential QC elements to be addressed in any case. This issue is still under discussion and this paragraph may be amended.

In 5.11.3.d, a tracking system is required but the requirements for the information to be stored in this system may be duplicative if the information is already contained elsewhere. This seems to be dictating to laboratories what to store in their tracking system. The committee will revisit this language.

Section 5.11.4.a.1 should more clearly state that the storage conditions should be above 0°C instead of stipulating a minimum temperature of 0.1°C. The committee will revisit this section.

**ACTION ITEMS**  
**Quality Systems Committee**  
**January 13, 1998**

<b>Item No.</b>	<b>Action Item</b>	<b>Date to be Completed</b>
1.	Consider changes as a result of Tuesday's meeting	February 4, 1998
2.	Consider input of any written comments	Through April, 1998
3.	Next QS teleconference	2/4/98, 1 p.m.
4.	Plan face to face meeting for QS Committee	End of March to early April, 1998
5.	Written comments due to QS Committee	2/15/98
6.	Convene air subcommittee to review air issues related to QS	Immediate

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**January 13, 1998**

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